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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,793	10/24/2003	Jerome B. Zeldis	9516-080-999	2026

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222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,793	ZELDIS ET AL.	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 5, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *3-21,24,25 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,22,23 and 26-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed September 5, 2008 have been received and entered into the application.

Action Summary

The rejection of claim 31 under 35 U.S.C. **112, second** paragraph, as being indefinite is being **maintained** for the reasons stated in the previous Office Action.

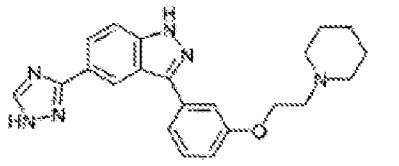
The rejection of claims 1, 28-35 under 35 U.S.C. **102(e)** as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1, 28-31 under 35 U.S.C. **102(e)** as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) evidenced by Sanders et al. (U.S. patent No. 5,766,605 A) or Mathias (U.S. patent No. 5,4341,36A) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1, 28-31 under 35 U.S.C. **102(e)** as being anticipated by Stein et al. (US 2004/0067953A1) is being **maintained** for the reasons stated in the previous Office Action.

Applicant's are reminded of Applicants' election **without traverse** of Group I, claims 1, 2, 5-11, 22, 23 and 26-35 drawn to a method for treating, preventing managing and/or modifying pain in a patient, comprising administering to a patient in need there of an effective amount of a compound having the formula set forth in claims 2, 5-11 and 23

with an election of species of 3-(3-(2-(piperidin-1-yl)ethoxy)phenyl)-5-(1H-1,2,4-triazol-3-yl)-1H-1H-indazole having the following structure:



3-[3-(2-Piperidin-1-yl-ethoxy)-phenyl]-5-(1*H*-[1,2,4]triazol-3-yl)-1*H*-indazole ;

Claims 1, 2, 22, 23 and 26-35 have been examined only to the extent of applicants' elected species of 3-(3-(2-(piperidin-1-yl)ethoxy)phenyl)-5-(1H-1,2,4-triazol-3-yl)-1H-1H-indazole.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "**..pain is… lost hair, dry hand, color change to the skin, weakness, edema, increased sweating..etc**" renders the claim vague and indefinite because above conditions that equates the term "pain" where applicants act as his or her own lexicographer to specifically define a term of a claim **contrary to its ordinary**

meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "**"pain**" in claim 31 is used by the claim to mean "**lost hair, dry hand, color change to the skin, weakness, edema, increased sweating..etc**", while the accepted meaning is "pain, hyperalgesia, nociception etc.." The term is indefinite because the specification does not clearly redefine the term.

The phrase "**another** painful neuropathic condition" renders the claim vague because it is not clear that **"another"** painful neuropathic condition is intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 28-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) evidenced by Andersen et al. (U.S.Patent No. 5,712,292).

Bhagwat et al. teach that Applicants' active agent is useful for the treatment of stroke, asthma, osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemical radiation, traumatic injury and lupus erythematosus, diabetes and cancers of a variety of tissues.

Andersen et al. disclose that **painful conditions** are exemplified by migraine, postoperative pain, **burns,** bruises, post-herpetic pain and pain is generally associated with acute inflammation; chronic, painful and/or inflammatory conditions exemplified by various types of neuropathy (**diabetic, post traumatic**, toxic), neuralgia, **rheumatoid arthritis**, spondylitis, **gout**, inflammation bowel disease, prostatitis, cancer pain, chronic headache coughing, **asthma**, **inflammatory skin disease** including psoriasis and **autoimmune dermatoses**, osteoporotic pain. (column 2, lines 62-67).

Accordingly, the claims are clearly anticipated by the cited reference because the subject population "experiencing pain" to be treated are the same as the term is defined in claim 31 as those painful conditions taught by Bhagwat et al. It is noted that Bhagwat et al. teach that Applicants' active agent is useful for treatment of osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemicals radiation, traumatic injury and cancer exhibit/develop pain. Therefore, patients disclosed by Bhagwat et al. are "experiencing pain" as instantly claimed. In this case the Bhagwat et al. methodology and the disorders to be treated meets all elemental steps of the instant

claims, accordingly, Bhagwat et al. inherently achieve all functional clinical effects subsequent to the administration of the same active agent to the same subject population (experiencing having the conditions). Since Bhagwat et al's method steps and the disease experienced by the patients disclosed by Bhagwat et al. are the same, Bhagwat et al.'s method inherently achieve the same clinical results instantly claimed.

Claims 1, 2 and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhagwat et al. (U.S.Patent No. 6,897,231 B2) evidenced by Sanders et al. (U.S. patent No. 5,766,605 A) or Mathias (U.S. patent No. 5,4341,36A) and by Andersen et al. (U.S.Patent No. 5,712,292).

Bhagwat et al. teach that Applicants active agent is useful for the treatment and prevention of lupus erythematosus and asthma.

Applicants claiming the treatment of pain equates to a "complex regional pain syndrome" as an **autonomic dysfunction**.

Sanders et al. teach that asthma is autonomic dysfunction. (abstract, claim 1)

Mathias teaches that Lupus Erythematosus is an autonomic dysfunction. (column 1, lines 11-20).

Andersen et al. disclose that **painful conditions** are exemplified by migraine, postoperative pain, **burns,** bruises, post-herpetic pain and pain is generally associated with acute inflammation; chronic, painful and/or inflammatory conditions exemplified by various types of neuropathy (**diabetic, post traumatic**, toxic), neuralgia, **rheumatoid**

arthritis, spondylitis, **gout**, inflammation bowel disease, prostatitis, cancer pain, chronic headache coughing, **asthma**, **inflammatory skin disease** including psoriasis and **autoimmune dermatoses**, osteoporotic pain. (column 2, lines 62-67).

Accordingly, the claims are clearly anticipated by the cited reference because the subject population "experiencing pain" are the same. Bhagwat et al. teach that **Applicants' active agent is useful for treatment of lupus erythematosus and asthma equate to pain set forth in claim 31**. Therefore, patients disclosed by Bhagwat et al. are "experiencing pain as instantly claimed. In this case the Bhagwat et al. methodology meets all elemental steps of the instant claims, accordingly, Bhagwat et al. inherently achieve all functional clinical effects subsequent to the administration of the same active agent to the same subject population (experiencing pain). Since Bhagwat et al's method steps and the disease experienced by the patients disclosed by Bhagwat et al. are the same, Bhagwat et al.'s method inherently achieve the same clinical results instantly claimed. Therefore, Bhagwat et al. clearly anticipates Applicants' claiming invention.

Claims 1, 2 and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Stein et al. (US 2004/0067953A1).

Stein et al. teach the treatment of cancer by the administration of an effective amount of Applicant's active agent. (abstract, Figure 6, C). Stein et al. teach that the active agent ameliorates symptoms associated with cancer. [0089].

Accordingly, the claims are clearly anticipated by the cited reference because the subject population "experiencing pain, wherein the pain is associated with cancer" are the same. Stein et al. teach the treatment of cancer and any symptoms associated with cancer by the administration of an effective amount of Applicant's active agent. Therefore, patients disclosed by Stein et al. are "experiencing pain" is encompassed by the treatment of any symptoms associated with cancer because it is well known in the art that pain is associated with cancer. In this case the Stein et al. methodology meets all elemental steps and conditions that is associated with cancer, accordingly, Stein et al. inherently achieve all functional clinical effects subsequent to the administration of the same active agent to the same subject population (experiencing a symptom associated with cancer). Since Stein et al's method steps are the same and encompasses the treatment of any symptoms that are associated with cancer, Stein et al.'s method inherently achieves the same clinical results instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 23, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. (U.S.Patent No. 6,897,231 B2).

Bhagwat et al's teaching as applied as before. Bhagwat et al. teach that compounds can be administered together with another biologically active agent. (particularly column 24, line 40). Bhagwat et al. teach that the compound can be formulated with a local anesthetic such as Lignocaine to ease pain at the site of the injection. (column 26, lines 25-30).

Bhagwat et al. do not teach the specific agents set froth in claim 27.

It would have been obvious to one of ordinary skill in the art to combine an anesthetic including ketamine with Bhagwat et al's compound because Bhagwat et al. teach that any biologically active agent can be combined with Bhagwat et al's compound and because a local anesthetics can ease pain at the site of the injection. One would have been motivated to combine any anesthetic such as ketamine together with Bhagwat et al's compound in order to avoid pain at the injection site by combining an local anesthetic including ketamine.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed September 5, 2008 have been fully considered but they are not persuasive. With regard to 35 U.S.C.112, second paragraph rejection, Applicants argue that claim 31 has been amended to recite that the pain can be "associated with" recited conditions to overcome the rejection. This is not found persuasive because the claim as amended still equates the term "pain" that is contrary to its ordinary meaning. (see the rejection). Therefore, the term is indefinite because the specification does not clearly redefine the term as such.

With respect to 35 U.S.C. 102(e) rejection over U.S.Patent No. 6,897,231 B2 (Bhagwat et al.), Applicants essentially argue that the literature references and examples discussed to demonstrate that pain and any underlying condition are separate entities with respect to their treatment and that pain itself should be considered as a disease in its own right. Applicants also argue that the claims 1 and 2 have been amended to recite method for treatment. This is not persuasive because Applicants literature references and examples submitted to demonstrate that pain and any underlying condition are separate entities, they contradict with what is instantly claimed, for examples claim 31 equates all of the underlying disease equate to pain. Further, the claims as amended are anticipated by the cited reference because the subject

population "experiencing pain" to be treated are the same. Bhagwat et al. teach that Applicants' active agent is treatment of osteoarthritis, rheumatoid arthritis, gout, burn from exposure to fire, chemicals radiation, traumatic injury and cancer exhibit/develop pain. Therefore, patients disclosed by Bhagwat et al. encompass the same subject population "experiencing pain" as instantly claimed.

With respect to 35 U.S.C. 102(e) rejection over U.S.Patent No. 6,897,231 B2 (Bhagwat et al.), evidenced by U.S.Patent No. 5,766,605 or U.S.Patent No. 5,434,136; and 35 U.S.C. 102(e) rejection over (U.S.2004/0067953A1), Applicants essentially argue that the claims 1 and 2 have been amended to recite method of treatment to overcome rejections. This is not found to be persuasive because the claim as amended still equates the term "pain" with those underlying disease such as cancer, asthma and lupus erythematosus. (see claim 31). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
December 16, 2008